IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: TRICOR DIRECT PURCHASER ANTITRUST LITIGATION	)	
THIS DOCUMENT RELATES TO:	)	Civil Action No. 05-340 (KAJ)
American Sales Company (06-192)	)	CONSOLIDATED

ABBOTT'S ANSWER TO PLAINTIFF AMERICAN SALES COMPANY'S COMPLAINT

Defendant Abbott Laboratories ("Abbott"), by its undersigned attorneys, hereby answers American Sales Company, Inc.'s ("Plaintiff" or "American Sales") Complaint, on knowledge as to itself and otherwise on information and belief, as follows:

1. Admit that Defendants manufacture and sell a fenofibrate drug product marketed under the tradename TriCor and that the first sentence of paragraph 1 provides a non-exhaustive description of TriCor. Additionally, Paragraph 1 contains a description of this proceeding and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 1.

2. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 2 and therefore denies them.

3. Admitted.

4. Admitted.

5. Denied.

6. Admit only that plaintiff purports to bring this action under the identified statutes and that this Court has subject-matter jurisdiction over Abbott.

7. Admit only that venue is proper in this judicial district as to Abbott.

8. Admit that TriCor is sold in interstate commerce. Abbott otherwise denies the allegations in paragraph 8.

9. Paragraph 9 contains descriptive narrative and legal conclusions that requires no answer. Abbott otherwise denies the allegations in paragraph 9.

10. Paragraph 10 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 10.

11. Paragraph 11 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 11.

12. Paragraph 12 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 12.

13. Paragraph 13 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in Paragraph 13.

14. Denied.

15. Denied.

16. Paragraph 16 contains legal conclusions that require no answer.

17. Paragraph 17 contains legal conclusions that require no answer.

18. Paragraph 18 contains legal conclusions that require no answer.

19. Paragraph 19 contains descriptive narrative and legal conclusions that require no answer.

20. Paragraph 20 contains descriptive narrative and legal conclusions that require no answer.

21. Paragraph 21 contains legal conclusions that require no answer.

22. Paragraph 22 contains legal conclusions that require no answer.

23. Paragraph 23 contains legal conclusions that require no answer.

24. Paragraph 24 contains legal conclusions that require no answer.

25. Paragraph 25 contains legal conclusions that require no answer.

26. Paragraph 26 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 26.

27. Paragraph 27 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 27.

28. Paragraph 28 contains descriptive narrative and legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 28.

29. Admit that paragraph 29 contains a non-exhaustive description of TriCor.

30. Admit that fenofibrate is a fibrate and that fibrates, statins, bile acid sequestrants, and niacin are cholesterol-lowering drugs. Abbott otherwise denies the allegations in paragraph 30.

31. Admit that fenofibrate has been known to be a cholesterol-lowering agent since at least the early 1980's and that Fournier's fenofibrate-based drug product Lipidil was approved for use in the United States by at least 1993. Abbott otherwise denies the allegations in paragraph 31.

32. Paragraph 32 contains legal conclusions that require no answer. To the extent that Paragraph 32 describes U.S. Patent No. 4,895,726 ("'726 patent"), its prosecution history or its reexamination history, Abbott states that the '726 patent, prosecution history and reexamination history speak for themselves. Abbott otherwise denies the allegations in paragraph 32.

33. Paragraph 33 contains legal conclusions that require no answer. To the extent that Paragraph 33 describes the '726 patent, its prosecution history or its reexamination history, Abbott states that the '726 patent, prosecution history and reexamination history speak for themselves. Abbott otherwise denies the allegations in paragraph 33.

34. Admit that in Fournier filed for reexamination of the '726 patent in December 1999. To the extent that Paragraph 34 describes the reexamination history of the '726 patent, Abbott states that the reexamination history speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 34.

35. Admit that (i) Fournier granted Abbott an exclusive license to the '726 patent in the United States in 1997, (ii) the FDA approved the TriCor 67 mg capsule on February 9, 1998, (iii) the FDA approved TriCor 134 mg and 200 mg capsules on June 30, 1999 and (iv) sales of TriCor exceeded $150 million in 2000 and $250 million in 2001. Abbott otherwise denies the allegations in paragraph 35.

36. Admit only that (i) Novopharm filed an ANDA with the FDA on or around December 14, 1999 for fenofibrate capsule, (ii) the ANDA was later amended, and (iii) Novopharm submitted paragraph IV certifications. To the extent that Paragraph 36 describes the ANDA and the paragraph IV certification, Abbott states that the documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 36.

37. Admit only that Impax (i) filed an ANDA with the FDA for fenofibrate capsules on or around May 9, 2000 and (iii) submitted paragraph IV certifications. To the extent that Paragraph 37 describes the ANDA and the paragraph IV certification, Abbott states that the documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 37.

38. Admit that Abbott and Fournier filed complaints alleging infringement of the '726 patent against Teva and Impax in the United States District Court of the District of Illinois on or about April 7, 2000, August 18, 2000, and March 19, 2001. The complaints speak for themselves and should be read as a whole. Additionally, paragraph 38 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 38.

39. Admit that the FDA granted Impax tentative approval for Impax's fenofibrate capsules on or around February 20, 2002. Additionally, paragraph 39 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 39.

40. Admit that the Illinois District Court granted summary judgment of non-infringement in favor of Teva and that, on March 20, 2003, the U.S. Court of Appeals for the Federal Circuit ruled on the appeal of the trial court's decision in *Abbott Laboratories v. Novopharm Ltd.*, 2002 WL 433584 (N.D. Ill. Mar. 20, 2002). Paragraph 40 contains legal conclusions that require no answer. To the extent Paragraph 40 describes the Illinois District Court opinion in *Abbott Laboratories v. Novopharm Ltd.*, 2002 WL 433584 (N.D. Ill. Mar. 20, 2002) or the Federal Circuit opinion, Abbott states that the opinions speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 40.

41. Admit that (i) Teva received final FDA approval to market its 134 mg and 200 mg fenofibrate capsule product on April 9, 2002, (ii) tentative approval to market its 67 mg fenofibrate capsule product on April 9, 2002 and (iii) final approval to market its 67 mg fenofibrate capsule product on September 3, 2002. Abbott otherwise denies the allegations in paragraph 41.

42. Admit that (i) the Illinois District Court granted Impax's motion for summary judgment on March 26, 2003 and (ii) the FDA granted Impax final approval to market

its fenofibrate capsules on September 28, 2003. To the extent that Paragraph 42 describes the District Court's opinion, Abbott states that the opinion speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 42.

43. Denied.

44. Denied.

45. Admit that Abbott obtained FDA approval to market the 54 mg and 160 mg tablet TriCor formulation on September 4, 2001, and that Abbott had previously marketed the TriCor capsules. Abbott otherwise denies the allegations in paragraph 45.

46. Admit that Abbott discontinued the TriCor capsule formulation and that Abbott communicated the discontinuance to the public. Abbott otherwise denies the allegations in paragraph 46.

47. Denied.

48. Denied.

49. Admit that TriCor is a maintenance medication. Abbott otherwise denies the allegations in paragraph 49.

50. Admit that Teva received final FDA approval to market its 134 mg and 200 mg fenofibrate capsule product in April 2002. Abbott otherwise denies the allegations in paragraph 50.

51. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 51 regarding what physicians and pharmacies do and therefore denies them. Abbott otherwise denies the allegations in paragraph 51.

52. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 52 and therefore denies them.

53. Admit that Abbott communicated the discontinuance of the TriCor capsule formulation to First DataBank. Abbott otherwise denies the allegations in paragraph 53.

54. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 54 regarding retail pharmacy practices and therefore denies them. Abbott otherwise denies the allegations in paragraph 54.

55. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 55 regarding third-party plans and pharmacist practices and therefore denies them. Abbott otherwise denies the allegations in paragraph 551.

56. Admit only that the TriCor tablets (160 mg and 54 mg) are bioequivalent to the TriCor capsules and had common clinical studies. Abbott otherwise denies the allegations in paragraph 56.

57. Admit only that (i) the 160 mg and 54 mg TriCor tablet product contained an indication (HDL) not contained by the TriCor capsule product, (ii) the clinical studies supporting the indication were based on the TriCor capsule product, and (iii) that paragraph 57 purports to reference a FDA document. The document speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 57.

58. Denied.

59. Denied.

60. Denied.

61. Admit that Abbott and Fournier invested resources developing and obtaining FDA approval for the 54 mg and 160 mg TriCor tablet formulations. Abbott otherwise denies the allegations in paragraph 617.

62. Denied.

63. Denied.

64. Denied.

65. Admit that (i) Teva filed an ANDA for 54 mg and 160 mg fenofibrate tablets, (ii) the ANDA contained Paragraph IV certifications for the '726 patent and U.S. Patent Nos. 6,074,670 (the "'670 patent") and 6,277,405 (the "'405 patent"), and (iii) Abbott and Fournier received notice of Teva's Paragraph IV certification on August 21, 2002. Abbott otherwise denies the allegations in paragraph 65.

66. Admit that (i) Teva filed Paragraph IV certifications U.S. Patent Nos. 6,589,552 (the "'552 patent") and 6,652,881 (the "'881 patent"), (ii) Abbott and Fournier received notice of the Paragraph IV certifications, and (iii) Abbott and Fournier filed suit against Teva on the '552 and '881 patents within 45-days after receiving such notice. Abbott otherwise denies the allegations in paragraph 66.

67. Admitted.

68. Paragraph 68 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 68.

69. Admit that (i) Impax filed an ANDA for fenofibrate tablets in or around December 2002, (ii) the ANDA contained Paragraph IV certifications for the '726, '670 and '405 patents, and (iii) Abbott and Fournier filed a complaint against Impax alleging infringement of the '670 and '405 patents on January 23, 2003, and subsequently filed suits alleging infringement of the '552 and '881 patents. Paragraph 69 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 69.

70. Admit that the FDA granted tentative approval to Teva and Impax's ANDA's for 54 mg and 160 mg fenofibrate tablets on March 5, 2004, and that Teva and Impax

have represented to this Court that, absent the 30-month stays, they would have received final approval from the FDA on March 5, 2004 and would have entered the market shortly thereafter. Abbott otherwise denies the allegations in paragraph 70.

71. Abbott is without sufficient information or knowledge to form a belief as to the truth of the allegations in paragraph 71 regarding "likely" actions and therefore denies them. Abbott otherwise denies the allegations in paragraph 71.

72. Admit only that (i) Teva, Impax, Abbott and Fournier agreed to modifications of the original trial schedule, (ii) Abbott and Fournier moved to voluntarily dismiss the patent infringement complaint and Teva's and Impax's counterclaims on May 20, 2005, and (iii) Teva, Impax, Abbott and Fournier jointly stipulated to a dismissal of the patent infringement claims and counterclaims. Abbott otherwise denies the allegations in paragraph 72.

73. Denied.

74. Admit that Abbott and Fournier alleged that Teva and Impax infringed the '726 patent in the Illinois Patent Litigation. Abbott otherwise denies the allegations in paragraph 74.

75. To the extent Paragraph 75 describes the '726 patent, its prosecution history or its reexamination history, Abbott states that the '726 patent, the prosecution history and reexamination history speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 75.

76. To the extent Paragraph 76 describes Novopharm's or Teva's fenofibrate capsule ANDA or paragraph IV certification, Abbott states that the documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 76.

77. Denied.

78. Admit that Paragraph 78 purports to describe the district court and Federal Circuit decisions and quotes from the Federal Circuit decision. Abbott responds that the decisions speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 78.

79. Admits that Paragraph 79 purports to describe the district court opinion in *Abbott Laboratories v. Impax Laboratories, Inc.*, 2003 WL 1563426 (N.D. Ill. 2003), and quotes from the opinion. Abbott responds that the decision speaks for itself and should be read as a whole. Abbott otherwise denies the allegations in paragraph 79.

80. Admit that Abbott and Fournier initiated the patent infringement action against Teva for infringement of the '726, '670, '405, '552, and '881 patents. Abbott otherwise denies the allegations in paragraph 80.

81. Admit that Teva provided Abbott and Fournier with its Paragraph IV certifications and technical materials from its ANDA. Abbott otherwise denies the allegations in paragraph 81.

82. Denied.

83. Denied.

84. Paragraph 84 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 84.

85. Admit only that paragraph 85 purports to describe and quote from the Stamm Patents, Markman rulings and other filings in the Delaware Patent Litigation. Abbott states that these documents speak for themselves and should be read as a whole. Abbott otherwise denies the allegations in paragraph 85.

86. Paragraph 86 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 86.

87. Admit that the ‘881 patent resulted from Application No. 10/288,425, filed November 6, 2002; and the ‘881 patent is assigned to Fournier. Admit that Paragraph 87 purports to describe and quotes from the ‘881 patent. Abbott states that the patent and its prosecution history speak for themselves. Abbott otherwise denies the allegations in paragraph 87.

88. Admit that Fournier is the owner of the ‘726 patent and that paragraph 88 purports to describe the ‘726 patent. Abbott states that the ‘726 patent, its prosecution history and its reexamination history speak for themselves and should be read as a whole. Paragraph 88 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 88.

89. Admit that paragraph 89 purports to describe the ‘881 patent and quotes from it. Abbott states that the ‘881 patent and its prosecution history speak for themselves and should be read as a whole. Paragraph 89 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 89.

90. Admit that paragraph 90 purports to describe the ‘881 prosecution history and quotes from it. Abbott states that the ‘881 patent and its prosecution history speak for themselves and should be read as a whole. Paragraph 90 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 90.

91. Admit that paragraph 91 purports to describe the ‘881 prosecution history and quotes from it. Abbott states that the ‘881 patent and its prosecution history speak for

themselves and should be read as a whole. Paragraph 91 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 91.

92. Admitted.

93. Paragraph 93 contains legal conclusions that require no answer. To the extent paragraph 93 describes the '881 prosecution history, Abbott states that the '881 patent and its prosecution history speak for themselves. Abbott otherwise denies the allegations in paragraph 93.

94. Paragraph 94 contains legal conclusions that require no answer. To the extent paragraph 94 describes the '881 patent or its prosecution history, Abbott states that the '881 patent and its prosecution history speak for themselves. Abbott otherwise denies the allegations in paragraph 94.

95. Paragraph 95 contains legal conclusions that require no answer. Admit only that Paragraph 95 purports describe unspecified Fournier documents. Without a cite to a specific document, Abbott is without sufficient knowledge or information to form a belief as the to the truth of the allegations in paragraph 95 and therefore denies them. Abbott otherwise denies the allegations in paragraph 95.

96. Admit only that paragraph 96 purports to describe the prosecution history of the '881 patent. Abbott states that the '881 patent and its prosecution history speak for themselves and should be read as a whole. Additionally, paragraph 96 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 96.

97. Admit only that paragraph 97 purports to describe the prosecution history of the '881 patent. Abbott states that the '881 patent and its prosecution history speak for

themselves and should be read as a whole. Additionally, paragraph 97 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 97.

98. Admit only that paragraph 98 purports to describe the prosecution history of the '881 patent. Abbott states that the '881 patent and its prosecution history speak for themselves and should be read as a whole. Additionally, paragraph 98 contains legal conclusions that require no answer. Abbott otherwise denies the allegations in paragraph 98.

99. Paragraph 99 contains legal conclusions that require no answer.

100. Paragraph 100 contains legal conclusions regarding the "duty to disclose" and "material information" that require no answer. Admit only that Reginault signed an inventor's oath in connection with the '726 patent. Abbott states that the inventor's oath, and the '881 patent and its prosecution history speak for themselves and should be read as a whole. Abbott is without sufficient knowledge or information to form a belief as to Reginault's "aware[ness]" as alleged in paragraph 100 and therefore denies this allegation. Abbott otherwise denies the allegations in paragraph 100.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

105. Admit that Abbott obtained FDA approval on November 5, 2004, to market a new TriCor tablet formulation that contains the same active ingredient, fenofibrate, in 48 mg and 145 mg strengths. Abbott otherwise denies the allegations in paragraph 105.

106. Admit that (i) the new 48 and 145 mg tablet formulations allow patients to take TriCor without meals, and were developed using patented nanotechnology licensed from

Elan Corporation, Plc, and (ii) the patent license obtained from Elan was exclusive for the field of fenofibrate dosage forms. Abbott otherwise denies the allegations in paragraph 106.

107. Admit that Abbott discontinued the TriCor original tablet formulation when the new tablet formulation became available and communicated the tablet discontinuance to First Data Bank and to the public. Abbott otherwise denies the allegations in paragraph 107.

108. Denied.

109. Admit only that Abbott under certain circumstances accepted returns of the original tablet formulation. Additionally, paragraph 109 purports to describe unspecified Abbott documents. Without cites to specific documents, Abbott is without sufficient knowledge or information to form a belief as the to the truth of the allegations in paragraph 109 and therefore denies them. Abbott otherwise denies the allegations in paragraph 109.

110. Denied.

111. Denied.

112. Denied.

113. Denied.

114. Admit that the relevant geographic market is the United States. Abbott otherwise denies the allegations in paragraph 114.

115. Denied.

116. Denied.

COUNT ONE

MONOPOLIZATION (15 U.S.C. § 2)

117. Abbott incorporates by reference the responses contained in paragraphs 1 through 116 above.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

COUNT TWO

CONSPIRACY IN RESTRAINT OF TRADE (15 U.S.C. § 1)

123. Abbott incorporates by reference the responses contained in paragraphs 1 through 122 above.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

129. Denied.

130. Denied.

ADDITIONAL DEFENSES

ADDITIONAL DEFENSE NO. 1

American Sales' Complaint fails to state a claim against Abbott upon which relief may be granted.

ADDITIONAL DEFENSE NO. 2

American Sales has not suffered, and will not suffer, injury of the type that the antitrust laws are designed to prevent, or any other injury to a legally cognizable interest, by reason of the conduct alleged in its Complaint.

ADDITIONAL DEFENSE NO. 3

At all times, Abbott has acted in good faith in furtherance of its legitimate business interests and has caused no injury to competition, the public, or American Sales.

ADDITIONAL DEFENSE NO. 4

Abbott's conduct is protected under the Noerr-Pennington doctrine, the First Amendment, and/or otherwise under the Constitution of the United States.

ADDITIONAL DEFENSE NO. 5

American Sales' claims are precluded, in whole or in part, by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984 and related amendments.

ADDITIONAL DEFENSE NO. 6

American Sales' claims are barred, in whole or in part, because there have been no classwide damages as alleged by American Sales.

ADDITIONAL DEFENSE NO. 7

To the extent there is a finding of conduct that prevented generic entry and higher prices as a result, American Sales' claims are barred, in whole or in part, to the extent any higher prices were passed on, in whole or in part, to parties not included in the putative class.

ADDITIONAL DEFENSE NO. 8

American Sales' claims are barred, in whole or in part, because plaintiffs would be unjustly enriched if allowed to recover all or any part of the damages alleged in its Complaint.

ADDITIONAL DEFENSE NO. 9

American Sales' claims fail to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

ADDITIONAL DEFENSE NO. 10

American Sales did not suffer injury or damages by reason of any act or omission by Abbott.

ADDITIONAL DEFENSE NO. 11

American Sales' claims are barred, in whole or in part, because it failed to mitigate its damages.

ADDITIONAL DEFENSE NO. 12

Any injuries, losses, or damages suffered by American Sales were proximately caused by its own actions regardless of whether contributory, negligent, incompetent, careless or reckless.

ADDITIONAL DEFENSE NO. 13

American Sales' claims are barred, in whole or in part, because its alleged damages, if any, are speculative.

ADDITIONAL DEFENSE NO. 14

American Sales' claims are barred, in whole or in part, by the applicable statute of limitations and/or laches.

ADDITIONAL DEFENSE NO. 15

American Sales' claims are barred, in whole or in part, because of waiver and/or estoppel.

ADDITIONAL DEFENSE NO. 16

Abbott does not maintain monopoly power in the relevant market.

ADDITIONAL DEFENSE NO. 17

The Food and Drug Administration approved each version of TriCor for sale in the United States.

ADDITIONAL DEFENSE NO. 18

American Sales' claims are barred, in whole or in part, because they contravene the rule of law established by the United States Supreme Court in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977).

ADDITIONAL DEFENSE NO. 19

Abbott reserves the right to add to its additional defenses as additional information becomes available in the course of this litigation.

RELIEF REQUESTED

WHEREFORE, Abbott, having answered, respectfully requests judgment dismissing with prejudice the American Sales Complaint and each and every claim for relief therein, and awarding Abbott its costs, disbursements, attorneys' fees and such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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Dated: July 21, 2006
529722

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on July 21, 2006, the foregoing were caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on July 21, 2006 upon the following parties:

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The undersigned also hereby certifies that on July 21, 2006, true and correct copies of the foregoing were caused to be served by hand upon the following local counsel:

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